

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

GENBIOPRO, INC.,

Plaintiff,

v.

**MARK A. SORSAIA, in his official capacity
as Prosecuting Attorney of Putnam County
AND PATRICK MORRISEY, in his official
capacity as Attorney General of West Virginia,
Defendants.**

**Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)**

**PLAINTIFF GENBIOPRO'S SUPPLEMENTAL BRIEF REGARDING
NATIONAL PORK PRODUCERS COUNCIL v. ROSS**

TABLE OF CONTENTS

	Page
TABLE OF CONTENTS	i
TABLE OF AUTHORITIES	ii
INTRODUCTION	1
ARGUMENT	2
I. AS SIX JUSTICES AGREED IN <i>NATIONAL PORK</i> , A LAW THAT UNDULY BURDENS INTERSTATE COMMERCE, SUCH AS WEST VIRGINIA’S, VIOLATES THE COMMERCE CLAUSE	2
A. A Six-Justice Majority Voted To Retain <i>Pike</i> ’s Balancing Test And Confirmed That The Test Applies To Statutes Like West Virginia’s	4
B. <i>National Pork</i> Confirms That West Virginia’s Ban And Restrictions Violate The Commerce Clause	7
1. <i>National Pork</i> Confirmed That Laws Burdening A Market Requiring National Uniformity, As Congress Established For REMS Drugs, Violate The Commerce Clause	7
2. West Virginia’s Laws Ban Mifepristone And Thereby Impose A Severe Burden On Interstate Commerce.....	11
3. West Virginia’s Laws Impose Derivative Harms That Are Cognizable Burdens Under <i>Pike</i> —Including Harm to Health And Safety	12
II. <i>NATIONAL PORK</i> LIMITS EXTRATERRITORIAL REGULATION CLAIMS TO PRICING STATUTES.....	14
CONCLUSION.....	15

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Association for Accessible Meds. v. Frosh</i> , 887 F.3d 664 (4th Cir. 2018)	8
<i>Bibb v. Navajo Freight Lines, Inc.</i> , 359 U.S. 520 (1959).....	12
<i>Cavel Int’l, Inc. v. Madigan</i> , 500 F.3d 551 (7th Cir. 2007)	11
<i>CTS Corp. v. Dynamics Corp.</i> , 481 U.S. 69 (1987).....	8
<i>Dennis v. Higgins</i> , 498 U.S. 439 (1991).....	2
<i>Department of Revenue of Ky. v. Davis</i> , 553 U.S. 328 (2008).....	5, 7
<i>Dobbs v. Jackson Women’s Health Org.</i> , 142 S. Ct. 2228, 2243 (2022)	10
<i>Exxon Corp. v. Governor of Md.</i> , 437 U.S. 117 (1978).....	8
<i>General Motors Corp. v. Tracy</i> , 519 U.S. 278 (1997).....	1, 5, 8
<i>Healy v. Beer Inst.</i> , 491 U.S. 324 (1989).....	15
<i>H. P. Hood & Sons, Inc. v. Du Mond</i> , 336 U.S. 525 (1949).....	14
<i>Hughes v. Oklahoma</i> , 441 U.S. 322 (1979).....	10, 14
<i>Kassel v. Consolidated Freightways Corp.</i> , 450 U.S. 662 (1981).....	12
<i>National Pork Producers Council v. Ross</i> , No. 21–468, — S. Ct. —, 2023 WL 3356528 (U.S. May 11, 2023)	<i>passim</i>

6 F.4th 1021 (9th Cir. 2021)	9, 15
<i>Pike v. Bruce Church, Inc.</i> , 397 U.S. 137 (1970).....	1, 2, 4
<i>Raymond Motor Transp., Inc. v. Rice</i> , 434 U.S. 429 (1978).....	12
<i>Schollenberger v. Pennsylvania</i> , 171 U.S. 1 (1898).....	4, 11
<i>United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.</i> , 550 U.S. 330 (2007).....	7
<i>Yamaha Motor Corp., U.S.A. v. Jim’s Motorcycle, Inc.</i> , 401 F.3d 560 (4th Cir. 2005)	3, 8

STATUTES

Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823	3
§ 505-1(f), 121 Stat. at 930-31	9
§ 505-1(f)(2)(D)(ii), 121 Stat. at 930.....	14
§ 505-1(f)(5)(B)(ii), 121 Stat. at 931	3
§ 505-1(f)(5)(B)(iii), 121 Stat. at 931	3
21 U.S.C. § 355-1(a)(1)(A)-(E)	14
21 U.S.C. § 355-1(f)	9
21 U.S.C. § 355-1(f)(2)(C)	4, 9, 10
21 U.S.C. § 355-1(f)(2)(C)(i).....	14
21 U.S.C. § 355-1(f)(2)(D).....	3, 8, 9, 10
W. Va. Code § 16-2I-2	1
W. Va. Code § 16-2R-1 <i>et seq.</i>	1
W. Va. Code § 30-1-26(b)(9).....	1
W. Va. Code § 30-3-13a(g)(5).....	2
W. Va. Code § 61-2-8	1

OTHER AUTHORITIES

Brief for Fed. Appellants, <i>Alliance for Hippocratic Med. v. FDA</i> , No. 23-10362 (5th Cir. Apr. 26, 2023), Dkt. 222	13
Letter from Patrizia A. Cavazzoni, Dir., U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., to Donna J. Harrison, Exec. Dir., Am. Ass’n of Pro-Life Obstetricians & Gynecologists, & Quentin L. Van Meter, President, Am. Coll. of Pediatricians at 6 (Dec. 16, 2021), https://www.regulations.gov/ document/FDA-2019-P-1534-0016	3
U.S. Food & Drug Admin., <i>2011 Mifeprex (Mifepristone) REMS</i> , https://www.accessdata.fda.gov/drugsatfda_docs/remes/Mifeprex_2011-06-08_ Full.pdf (last visited May 19, 2023).....	10

INTRODUCTION

The Supreme Court’s decision in *National Pork Producers Council v. Ross* reaffirmed the Court’s 50-year-old balancing test for dormant Commerce Clause claims: when a nondiscriminatory state law places a burden on interstate commerce that clearly exceeds its local benefits, that law violates the Commerce Clause. No. 21–468, — S. Ct. —, 2023 WL 3356528, at *18 (U.S. May 11, 2023) (Roberts, C.J., concurring in part and dissenting in part); *id.* at *17 (Sotomayor, J., concurring in part). A six-Justice majority held courts should apply this undue burden test, first articulated in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), even when doing so requires them to “weigh disparate burdens and benefits,” such as asserted moral interests and interference with interstate commerce. *National Pork*, 2023 WL 3356528, at *17 (Sotomayor, J., concurring in part); *see id.* at *19 (Roberts, C.J., concurring in part and dissenting in part).

The same majority agreed that *Pike*’s balancing test applies not just when traditional instrumentalities of commerce, like trains, are at issue, but whenever a state statute interferes with interstate commerce. *Id.* at *17 (Sotomayor, J., concurring in part); *id.* at *19 (Roberts, C.J., concurring in part and dissenting in part). The burdens on interstate commerce are particularly salient in “area[s] presenting a strong interest in ‘national uniformity.’” *Id.* at *20 (Roberts, C.J., concurring in part and dissenting in part) (quoting *General Motors Corp. v. Tracy*, 519 U.S. 278, 298 n.12 (1997); *see id.* at *17 (Sotomayor, J., concurring in part) (same)).

Under the framework affirmed in *National Pork*, West Virginia’s Unborn Child Protection Act, W. Va. Code § 16-2R-1 *et seq.*, and associated penalties, *id.* § 61-2-8 (collectively, the “Criminal Abortion Ban” or “Ban”), and abortion restrictions¹ violate the

¹ W. Va. Code §§ 16-2I-2 (requiring waiting period and counseling before an abortion procedure), 30-1-26(b)(9) (prohibiting providers from prescribing mifepristone via

Commerce Clause. These laws impose a severe burden on interstate commerce by functionally banning an article of commerce—mifepristone. The laws impede the flow of commerce into and around West Virginia, disrupting the market for a drug that Congress subjected to nationally uniform federal regulation. And the laws impose “derivative harms” cognizable under the Commerce Clause by depriving West Virginians of access to an essential healthcare product. *National Pork*, 2023 WL 3356528, at *20 (Roberts, C.J., concurring in part and dissenting in part). These direct burdens on interstate commerce and derivative harms outweigh the State’s alleged interest in passing the Ban and Restrictions.

ARGUMENT

I. AS SIX JUSTICES AGREED IN *NATIONAL PORK*, A LAW THAT UNDULY BURDENS INTERSTATE COMMERCE, SUCH AS WEST VIRGINIA’S, VIOLATES THE COMMERCE CLAUSE

The Commerce Clause “confer[s] a ‘right’ to engage in interstate trade free from restrictive state regulation.” *Dennis v. Higgins*, 498 U.S. 439, 448 (1991). In *National Pork*, a majority of the Supreme Court reaffirmed the rule, set forth in *Pike*, that when the “burden imposed on [interstate] commerce” by a state law “is clearly excessive in relation to the putative local benefits,” the law violates the Commerce Clause. *National Pork*, 2023 WL 3356528, at *16 (Sotomayor, J., concurring in part) (quoting *Pike*, 397 U.S. at 142); *see id.* (rejecting any “fundamental reworking” of the *Pike* “doctrine”); *id.* at *18 (Roberts, C.J., concurring in part and dissenting in part) (“Today’s majority does not pull the plug [on *Pike*’s balancing test].”).

All Justices recognized that the Court has invalidated laws under the Commerce Clause in cases implicating the “arteries” and “instrumentalities” of commerce, such as interstate transportation. *Id.* at *11 n.2 (majority opinion.); *id.* at *17 (Sotomayor, J., concurring in part);

telemedicine), 30-3-13a(g)(5) (providing for rule banning prescribing mifepristone via telemedicine) (collectively, the “Restrictions”).

id. at *18-19 (Roberts, C.J., concurring in part and dissenting in part). A six-Justice majority confirmed that a state law regulating products other than the traditional instrumentalities of commerce, such as the cantaloupe packaging at issue in *Pike*, may likewise violate the Commerce Clause if the burdens the law places on interstate commerce clearly exceed its local benefits. *Id.* at *17 (Sotomayor, J., concurring in part); *id.* at *19 (Roberts, C.J., concurring in part and dissenting in part). A state law may fail *Pike*’s balancing test, too, when it interferes in an arena requiring nationally uniform regulation at the federal level. *Id.* at *20 (Roberts, C.J., concurring in part and dissenting in part); *id.* at *17 (Sotomayor, J., concurring in part).

West Virginia’s Ban and Restrictions fail this test. First, they regulate “in an area where there is a compelling need for national uniformity,” *Yamaha Motor Corp., U.S.A. v. Jim’s Motorcycle, Inc.*, 401 F.3d 560, 572 (4th Cir. 2005): the “health care delivery system” for drugs subject to a Risk Evaluation and Mitigation Strategy (“REMS”), 21 U.S.C. § 355-1(f)(2)(D). Congress subjected this small subset of drugs to the comprehensive postmarket regulatory regime it established in the Food and Drug Administration Amendments Act of 2007 (“FDAAA”), Pub. L. No. 110-85, 121 Stat. 823, which requires the drugs to move through interstate commerce. *See, e.g., id.* § 505-1(f)(2)(D)(ii), 121 Stat. at 930 (requiring that any restrictions “be designed to be compatible with established distribution, procurement, and dispensing systems for drugs”); *id.* § 505-1(f)(5)(B)(ii), (iii), 121 Stat. at 931 (requiring that any restrictions not “unduly burden[] . . . patient access to the drug” and “minimize the burden on the health care delivery system”). This regime dictates in detail how such drugs move through interstate commerce, from packaging to distribution to dispensing. *See* Compl. ¶¶ 48-50; *see also* Plaintiff’s Opposition to Defendant Patrick Morrissey’s Motion to Dismiss at 23-24 (Mar. 17, 2023) (“Opp. to Morrissey MTD”), Dkt. 35; Letter from Patrizia A. Cavazzoni, Dir., U.S.

Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., to Donna J. Harrison, Exec. Dir., Am. Ass’n of Pro-Life Obstetricians & Gynecologists, & Quentin L. Van Meter, President, Am. Coll. of Pediatricians at 6 (Dec. 16, 2021) (explaining FDA’s determination that allowing mifepristone to be dispensed by mail “will render the REMS less burdensome to healthcare providers and patients”), <https://www.regulations.gov/document/FDA-2019-P-1534-0016>.

Second, West Virginia’s laws do not incidentally regulate interstate commerce in this arena; they impose a total ban by forbidding mifepristone in almost all circumstances for its indicated use. Courts have long recognized that product bans work a severe burden on interstate commerce. *See Schollenberger v. Pennsylvania*, 171 U.S. 1, 12 (1898). Finally, besides burdening “integral healthcare distribution mechanisms,” such as drug manufacturers, nationwide pharmacies, and online pharmacies, Compl. ¶ 78, the Ban and Restrictions inflict serious “derivative harms,” *National Pork*, 2023 WL 3356528, at *20 (Roberts, C.J., concurring in part and dissenting in part), depriving patients of access to FDA-approved, lifesaving healthcare that Congress prioritized for “patient access” nationwide, 21 U.S.C. § 355-1(f)(2)(C). GenBioPro alleges these harms to interstate commerce and derivative harms. *See* Compl. ¶¶ 1, 15-17, 39, 78-79, 104, 106-110.

A. A Six-Justice Majority Voted To Retain *Pike*’s Balancing Test And Confirmed That The Test Applies To Statutes Like West Virginia’s

When a state “statute regulates even-handedly to effectuate a legitimate local public interest,” the *Pike* balancing test asks judges to determine whether the “burden” the law imposes on interstate commerce “is clearly excessive” in relation to the law’s “putative local benefits.” *National Pork*, 2023 WL 3356528, at *16 (Sotomayor, J., concurring in part) (quoting *Pike*, 397 U.S. at 142). If the law’s burden outweighs its benefits, the law violates the Commerce Clause.

On May 11, 2023, the Supreme Court unanimously reaffirmed that *Pike*'s balancing of the burden on interstate commerce in relation to local benefits remains the operative test for evaluating whether a state law violates the Commerce Clause.² Six Justices would apply *Pike* to cases like this one, where the law does not discriminate in pricing and requires the court to balance burdens on interstate commerce and noneconomic interests. Chief Justice Roberts, writing for four Justices, stated that the *Pike* analysis "reflects the basic concern of our Commerce Clause jurisprudence that there be 'free private trade in the national marketplace.'" *Id.* at *18 (Roberts, C.J., concurring in part and dissenting in part, joined by Alito, Kavanaugh & Jackson, JJ.) (quoting *Tracy*, 519 U.S. at 287). He emphasized that *Pike* protects "a national 'common market'" and that courts can readily apply its framework, as they have for 50 years. *Id.* at *18-19 (quoting *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 350 (1977)).

Justice Sotomayor, joined by Justice Kagan, echoed Chief Justice Roberts's confidence in judges' ability to conduct *Pike* balancing, including when they must balance "economic burdens against noneconomic benefits." *Id.* at *17 (Sotomayor, J., concurring in part and holding that judges are "up to the task that *Pike* prescribes"). She observed that "courts generally are able to weigh disparate burdens and benefits against each other, and . . . they are called on to do so in

² All Justices analyzed the pork producers' claim under *Pike*; they disagreed only on the outcome of the undue burden test (or whether the Court could conduct the test at all) on the facts alleged in the operative complaint. Justice Gorsuch, writing in Part IV.A for the majority, acknowledged that "even nondiscriminatory burdens" a statute places on interstate commerce may fail under *Pike*. *National Pork*, 2023 WL 3356528, at *11 (majority opinion) (quoting *Department of Revenue of Ky. v. Davis*, 553 U.S. 328, 353 (2008)). But Justices Gorsuch, Thomas, and Barrett would hold that *Pike*'s balancing is "a task no court is equipped to undertake" when "[t]he competing goods are incommensurable," as with moral and health interests (animal welfare) versus dollars and cents (burden on pork producers). *Id.* at *13. Theirs is the minority view.

other areas of the law with some frequency.” *Id.* But applying that test, these two Justices concluded that the pork producers’ Commerce Clause claim foundered because they “fail[ed] to allege a substantial burden on interstate commerce”—“a threshold requirement” of *Pike*. *Id.* at *16.

Chief Justice Roberts and Justices Alito, Kagan, Sotomayor, Kavanaugh, and Jackson thus make up a majority of the Court holding that the *Pike* framework governs Commerce Clause challenges to laws that do not discriminate against out-of-state commerce, including those requiring judges to balance burdens on commerce with states’ asserted noneconomic interests. This six-Justice majority reaffirmed the Court’s long history of balancing disparate burdens and benefits in cases that implicate constitutional rights. *See id.* at *19 (Roberts, C.J., concurring in part and dissenting in part) (discussing cases). For example, Chief Justice Roberts explained that the Court has weighed “the purpose to keep the streets clean and of good appearance” against the “the constitutional protection of the freedom of speech and press,” *Schneider v. New Jersey (Town of Irvington)*, 308 U.S. 147, 162 (1939), and an individual’s Fourth Amendment interests in “privacy and security” against society’s interests in surgically removing a bullet from a suspect’s chest for evidentiary purposes, *Winston v. Lee*, 470 U.S. 753, 760 (1985); *see National Pork*, 2023 WL 3356528, at *19 (Roberts, C.J., concurring in part and dissenting in part). As the Chief Justice explained, “sometimes there is no avoiding the need to weigh seemingly incommensurable values.” *National Pork*, 2023 WL 3356528, at *19 (Roberts, C.J., concurring in part and dissenting in part).

The same six-Justice majority agreed that a state law need not discriminate against out-of-state companies or burden traditional “arteries of commerce,” like trucks and trains, to violate the Commerce Clause. *Id.* at *17 (Sotomayor, J., concurring in part); *see id.* at *19 (Roberts,

C.J., concurring in part and dissenting in part) (“As a majority of the Court agrees, *Pike* extends beyond laws either concerning discrimination or governing interstate transportation.”). Both opinions composing the majority cited *Edgar v. MITE Corp.*, 457 U.S. 624, 643-46 (1982), in which the Court held that an Illinois law requiring state approval for shareholder tender offers placed a “substantial” burden on interstate commerce that outweighed the state’s asserted interests in protecting securities holders. *National Pork*, 2023 WL 3356528, at *19 (Roberts, C.J., concurring in part and dissenting in part); *see id.* at *17 (Sotomayor, J., concurring in part). This approach reaffirmed precedent “leav[ing] the courtroom door open to plaintiffs invoking the rule in *Pike*, that even nondiscriminatory burdens on commerce may be struck down on a showing that those burdens clearly outweigh the benefits of a state or local practice.” *Department of Revenue of Ky. v. Davis*, 553 U.S. 328, 353 (2008); *see also United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 346 (2007) (plurality opinion) (*Pike* applies to “a nondiscriminatory statute like this one”).

B. *National Pork* Confirms That West Virginia’s Ban And Restrictions Violate The Commerce Clause

The Ban and Restrictions fail *Pike*’s balancing test for three reasons: (1) they intrude on an area in which Congress requires nationally uniform regulation; (2) they functionally ban a product for its indicated use; and (3) they inflict “derivative harms” by imperiling the health and safety of pregnant West Virginians and the national market for medications. That result is even clearer after *National Pork*.

1. *National Pork* Confirmed That Laws Burdening A Market Requiring National Uniformity, As Congress Established For REMS Drugs, Violate The Commerce Clause

All members of the Supreme Court held in *National Pork* that state laws may conflict with the Commerce Clause if they impose an excessive burden in an area requiring “national

uniformity.” *National Pork*, 2023 WL 3356528, at *20 (Roberts, C.J., concurring in part and dissenting in part) (quoting *Tracy*, 519 U.S. at 298 n.12); *id.* at *11 n.2 (majority opinion) (recognizing that the Commerce Clause can invalidate state regulation “when a lack of national uniformity would impede the *flow* of interstate goods”). If a statute serves a legitimate local interest, courts must balance that interest against the inherent burden created by regulating “in an area where there is a compelling need for national uniformity.” *Yamaha*, 401 F.3d at 572. A state law thus may fail *Pike*’s balancing test when it “adversely affect[s] interstate commerce by subjecting activities to inconsistent regulations.” *CTS Corp. v. Dynamics Corp.*, 481 U.S. 69, 88 (1987).

West Virginia’s laws burden “interstate commerce involving prescription drugs” subject to federal postmarket restrictions. *Association for Accessible Meds. v. Frosh*, 887 F.3d 664, 669-70 (4th Cir. 2018) (cited in *National Pork*, 2023 WL 3356528, at *9 (majority opinion)). The Ban and Restrictions impose “burden[s] on the health care delivery system” for these drugs in contravention of Congress’s mandate to reduce such burdens. *See* 21 U.S.C. § 355-1(f)(2)(D). They thereby cause “economic harms to the interstate market” that have “*market-wide* consequences.” *National Pork*, 2023 WL 3356528, at *19-20 (Roberts, C.J., concurring in part and dissenting in part).

West Virginia’s Ban and Restrictions go far beyond regulating the cantaloupe at issue in *Pike* or the sows in *National Pork*. They burden a market that Congress designated for national uniformity in regulation, bringing them into the heartland of the Commerce Clause. By regulating how mifepristone may be provided, dispensed, and prescribed, West Virginia’s laws affect the very “*flow*” of commerce for mifepristone. *Id.* at *11 n.2 (majority opinion) (quoting, with emphasis, *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 128 (1978)).

In *National Pork*, the negative effects on commerce the producers identified focused primarily on the fact that California’s law would require out-of-state pork producers to comply in order to maintain their business because of the interconnected nature of the national pork market, “mak[ing] pork production more expensive nationwide.” *National Pork Producers Council v. Ross*, 6 F.4th 1021, 1033 (9th Cir. 2021), *aff’d*, No. 21-468, 2023 WL 3356528 (U.S. May 11, 2023). But as the district court found, and the Supreme Court affirmed, the producers “fail[ed] to make a plausible allegation that the pork production industry is of such national concern that it is analogous to taxation or interstate travel, where uniform rules are crucial.” *Id.* at 1031. The key burden, in other words, was “the cost of compliance” with the statute. *Id.* at 1033. That is not true here. Drugs like mifepristone that treat serious medical conditions, and that FDA and Congress approved for distribution nationwide, are matters of national importance. Preventing patients from accessing those drugs threatens their lives and wellbeing, not just their pocketbooks.

Congress specifically required uniform federal regulation that is not “unduly burdensome on patient access” to REMS medications. 21 U.S.C. § 355-1(f)(2)(C). It required such regulation to “minimize the burden” on a key instrumentality of interstate commerce: “the health care delivery system.” *Id.* § 355-1(f)(2)(D). In the 2007 amendments to the Federal Food, Drug, and Cosmetic Act, Congress mandated that FDA alone may control how drugs subject to postmarket restrictions move through the interstate market from manufacturer to patient. *See generally* FDAAA § 505-1(f), 121 Stat. at 930-31 (codified at 21 U.S.C. § 355-1(f)); *Opp. to Morrissey MTD* at 10-11 & n.7.

Congress required FDA to work with drug sponsors like GenBioPro to develop and implement REMS incorporating drugs’ distribution schemes. The first REMS governing

Mifeprex (branded mifepristone) included regulations governing how the manufacturer should distribute the drug, including to whom it could be shipped, as has every REMS since. *See* U.S. Food & Drug Admin., *2011 Mifeprex (Mifepristone) REMS*, https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifeprex_2011-06-08_Full.pdf (last visited May 19, 2023). FDA can impose only restrictions that comply with Congress’s directive “to minimize the burden on the health care delivery system,” taking into account compatibility with “established distribution, procurement, and dispensing system for drugs,” and those restrictions must not be “unduly burdensome on patient access to the drug.” 21 U.S.C. § 355-1(f)(2)(C), (D). In requiring REMS drugs to be accessible via “the health care delivery system,” Congress expressed its intent that these drugs be available in, and flow through, channels of interstate commerce. West Virginia’s Ban and Restrictions contravene that intent by burdening the flow of mifepristone into and around the State.

Because Congress mandated a uniform system of regulation that minimizes the burden on the nationwide “health care delivery system” for REMS drugs, including mifepristone, GenBioPro’s Commerce Clause claim is stronger than that of the plaintiffs in *National Pork*. The “people’s . . . elected representatives” (Congress) have spoken. *Dobbs v. Jackson Women’s Health Org.*, 142 S. Ct. 2228, 2243 (2022). They provided in the FDAAA that REMS drugs must be accessible to patients and regulation must minimize burdens on the interstate “health care delivery system” for these drugs. *See* 21 U.S.C. § 355-1(f)(2)(D), (5)(A)(ii), (5)(B)(iii). States regulating REMS drugs in different ways, creating multiple markets with different rules and restrictions deviating from FDA’s considered judgment about safe use and access, is the very “economic Balkanization” the Framers ratified the Commerce Clause to prevent. *Hughes v. Oklahoma*, 441 U.S. 322, 325-26 (1979).

2. West Virginia's Laws Ban Mifepristone And Thereby Impose A Severe Burden On Interstate Commerce

A complete product ban imposes a particularly severe burden on interstate commerce, as the Supreme Court recognized more than a century ago. *Schollenberger*, 171 U.S. at 12. The Ban and Restrictions violate the Commerce Clause for this reason, too. In the years since *Schollenberger*, some courts have allowed states to prohibit importation of nonessential goods like foie gras, shark fins, or, as Justice Gorsuch highlighted, horsemeat. *E.g.*, *Cavel Int'l, Inc. v. Madigan*, 500 F.3d 551 (7th Cir. 2007) (horsemeat); *see National Pork*, 2023 WL 3356528, at *15 (majority opinion) (identifying fireworks, horsemeat, and plastic bags as consumer products states may ban).

These limited exceptions to *Schollenberger* have three things in common: (1) the products involved are not necessities (*never* FDA-approved drugs that address serious medical conditions), (2) they often cause severe harms or offer little public benefit, and (3) Congress did not subject these items to an integrated, and inherently national, system (here, for delivery of drugs and provision of medical services), much less limit “burdens” on that system. Horsemeat and shark fins fit those three criteria. Mifepristone fits none. No court has upheld a state ban of an FDA-approved medication essential for healthcare.

West Virginia's Ban is, in fact, a “Ban.” The Putnam Prosecuting Attorney admits as much. *See* Defendant Mark Sorsaia's Rule 12(b)(1) and Rule 12(b)(6) Motion to Dismiss at 2 (Feb. 16, 2023), Dkt. 17. The Attorney General (“WVAG”) responds to GenBioPro's allegations by denying that West Virginia has “banned mifepristone at all.” Reply in Support of Motion to Dismiss at 10 (Mar. 31, 2023) (“WVAG Reply”), Dkt. 45. He cites the fact that West Virginia does not attempt to regulate “off-label” use of mifepristone for conditions other than its FDA indication of termination of early abortion, and points to the Ban's limited exceptions. *Id.*

Whether these exceptions allow mifepristone to be sold and used in practice, and whether the possibility of off-label use saves the Ban from being a ban, are issues appropriately addressed on summary judgment. Hypothetical availability of “off-label” use does not mitigate the severe burden on its sales of mifepristone for its indicated use, or on the interstate commerce instrumentalities (pharmacies, telehealth) that deliver the drug.

3. West Virginia’s Laws Impose Derivative Harms That Are Cognizable Burdens Under *Pike*—Including Harm to Health And Safety

National Pork also undercuts the WVAG’s unsupported assertion that courts applying *Pike*’s balancing test cannot consider “noncommercial burdens allegedly imposed on third parties,” such as the burden GenBioPro alleges the Ban imposes on “West Virginians’ right to access lifesaving, safe, and necessary healthcare.” WVAG Reply at 10-11. Six Justices squarely rejected that argument in *National Pork*. As the Chief Justice explained, the “derivative harms” the Court has “long considered in this context” are cognizable burdens, “even if those burdens may be difficult to quantify.” *National Pork*, 2023 WL 3356528, at *20 (Roberts, C.J., concurring in part and dissenting in part) (citing *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 674 (1981) (plurality opinion), and *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429, 445 & n.21 (1978)).

Courts applying *Pike* routinely consider a challenged law’s effect on third parties and the public. *See, e.g., Kassel*, 450 U.S. at 674 (noting the significance of the fact that the challenged “law may aggravate . . . the problem of highway accidents” in describing the burden on interstate commerce); *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 527-28 (1959) (invalidating state regulation that caused derivative harms, including physical danger, delays, and significant labor time).

Here, West Virginia’s laws bring about “derivative harms” to pregnant West Virginians by depriving them of essential medicine. *National Pork*, 2023 WL 3356528, at *20 (Roberts, C.J., concurring in part and dissenting in part). That deprivation endangers West Virginians’ health and their lives: according to FDA and the U.S. Department of Health and Human Services (“HHS”), “pregnancy itself entails a significantly higher risk of serious adverse events [than medication abortion], including a death rate 14 times higher than that associated with legal abortion.” Brief for Fed. Appellants at 42, *Alliance for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 26, 2023), Dkt. 222. Such harms are a cognizable component of the Commerce Clause analysis. *National Pork*, 2023 WL 3356528, at *21 (Roberts, C.J., concurring in part and dissenting in part) (listing “worse health outcomes,” the spread of pathogens, and “consequential threats to animal welfare” among the relevant alleged harms) (brackets omitted).

The Ban and Restrictions functionally prevent West Virginians from accessing mifepristone for its indicated use, even though Congress tasked FDA with ensuring all Americans could access this drug for medication abortion. *See* Opp. to Morrissey MTD at 8-9; Brief of Food and Drug Law and Health Law Scholars as Amici Curiae in Support of Plaintiff’s Opposition to Defendants’ Motions to Dismiss at 8 & n.6 (Mar. 27, 2023), Dkt. 44 (“Congress was well aware that the ‘deemed to have in effect’ language [in the FDAAA] would sweep mifepristone into this new statutory scheme [and subject the drug to a REMS].”).

Aside from the harms the Ban and Restrictions cause pregnant people in West Virginia, these laws (and others like them) upend the national market for drugs. Manufacturers will hesitate to invest in developing drugs that they anticipate requiring a REMS when those drugs implicate salient political issues, based on concerns that states could close the doors of their markets. *See* Opp. to Morrissey MTD at 25; Compl. ¶ 17. The Commerce Clause ensures that

anyone who wants to manufacture a product in the United States “be encouraged to produce by the certainty that he will have free access to every market in the Nation.” *National Pork*, 2023 WL 3356528, at *18 (Roberts, C.J., concurring in part and dissenting in part) (quoting *H. P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 539 (1949)). States regulating REMS drugs in different ways, creating separate markets, is the kind of economic fracturing the Framers ratified the Commerce Clause to prevent. *See Hughes*, 441 U.S. at 325-26.

West Virginia’s interest in “unborn lives”—the only state interest mentioned in the statute, W. Va. Code § 16-2R-1—cannot overcome the burdens its Ban works on the interstate “health care delivery system” for mifepristone and on “access” to necessary healthcare for pregnant patients. *See* pp. 8-10, *supra*. Moreover, the REMS statute specifically requires the Secretary of HHS to consider the “seriousness” of patients’ “conditions” and the “expected benefit” to them in developing regulations on REMS drugs, thereby prioritizing the health of the patient in providing access to these medications. 21 U.S.C. § 355-1(a)(1)(A)-(E); *accord id.* § 355-1(f)(2)(C)(i) (requiring FDA, in imposing elements to assure safe use that are not “unduly burdensome on patient access to the drug,” to consider, among other factors, “patients with serious or life-threatening . . . conditions”). The State’s asserted interest cannot eclipse this congressional mandate. And it cannot outweigh Congress’s judgment that mifepristone must be accessible via interstate commerce. *See* pp. 9-10, *supra*.

II. NATIONAL PORK LIMITS EXTRATERRITORIAL REGULATION CLAIMS TO PRICING STATUTES

The plaintiffs in *National Pork* advanced an extraterritorial regulation theory premised on the idea that California’s pork rules impermissibly regulated out-of-state activities because the interconnected nature of the pork industry forces even non-California hog farmers to comply with California’s law. *See National Pork*, 2023 WL 3356528, at *6 (majority opinion); *see also*

National Pork, 6 F.4th at 1028. The Supreme Court unanimously rejected this argument and limited dormant Commerce Clause claims premised on extraterritorial regulation to statutes that discriminate against interstate commerce by tying in-state prices to out-of-state prices. *National Pork*, 2023 WL 3356528, at *9 (majority opinion). The Justices clarified that extraterritorial regulation claims based on *Healy v. Beer Institute*, 491 U.S. 324 (1989), and related cases must involve some element of “purposeful discrimination against out-of-state economic interests” linked to prices. *National Pork*, 2023 WL 3356528, at *8 (majority opinion).

West Virginia’s Ban and Restrictions are not price control or price affirmation statutes. GenBioPro therefore will not advance extraterritorial-regulation arguments.

CONCLUSION

The Supreme Court’s decision in *National Pork* strengthens GenBioPro’s Commerce Clause claim premised on the undue burden West Virginia’s laws impose on interstate commerce and the nationwide healthcare delivery system. For the foregoing reasons and those in GenBioPro’s Opposition to the Attorney General’s Motion to Dismiss, the Court should deny Defendants’ motions to dismiss.

Dated: May 19, 2023

Respectfully submitted,

David C. Frederick*
 Ariela M. Migdal*
 Eliana Margo Pfeffer*
 Mary Charlotte Y. Carroll*
 KELLOGG, HANSEN, TODD,
 FIGEL & FREDERICK, P.L.L.C.
 1615 M Street, N.W., Suite 400
 Washington, D.C. 20036
 Tel: (202) 326-7900
 dfrederick@kellogghansen.com
 amigdal@kellogghansen.com
 epfeffer@kellogghansen.com
 mcarroll@kellogghansen.com

/s/ Anthony J. Majestro
 Anthony J. Majestro
 WV Bar No. 5165
 Christina L. Smith
 W. Va. Bar No. 7509
 POWELL & MAJESTRO P.L.L.C.
 405 Capitol Street
 Suite P-1200
 Charleston, WV 25301
 Tel: (304) 346-2889
 amajestro@powellmajestro.com
 csmith@powellmajestro.com

Skye L. Perryman*
Kristen Miller*
DEMOCRACY FORWARD
FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
Tel: (202) 448-9090
sperryman@democracyforward.org
kmiller@democracyforward.org

John P. Elwood*
Daphne O'Connor*
Robert J. Katerberg*
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
john.elwood@arnoldporter.com
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

**admitted pro hac vice*

Counsel for Plaintiff GenBioPro, Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

GENBIOPRO, INC.,

Plaintiff,

v.

**MARK A. SORSAIA, in his official capacity
as Prosecuting Attorney of Putnam County
AND PATRICK MORRISEY, in his official
capacity as Attorney General of West Virginia,
Defendants.**

**Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)**

CERTIFICATE OF SERVICE

I, the undersigned, counsel for Plaintiff, GenBioPro, Inc., do hereby certify that on May 19, 2023, I electronically filed and served the foregoing **PLAINTIFF GENBIOPRO'S SUPPLEMENTAL BRIEF REGARDING *NATIONAL PORK PRODUCERS COUNCIL v. ROSS*** with the Clerk of the Court and all parties using the CM/ECF system.

Respectfully submitted,

/s/ Anthony J. Majestro

Anthony J. Majestro

WV Bar No. 5165

Christina L. Smith

W. Va. Bar No. 7509

POWELL & MAJESTRO P.L.L.C.

405 Capitol Street

Suite P-1200

Charleston, WV 25301

Tel: (304) 346-2889

amajestro@powellmajestro.com

csmith@powellmajestro.com

Counsel for Plaintiff GenBioPro, Inc.